UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE PFIZER INC. SHAREHOLDER DERIVATIVE LITIGATION	Master File No. 1:09-cv-7822 (JSR)

MEMORANDUM OF LAW IN SUPPORT OF THE INDIVIDUAL DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

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PRELIMINARY STATEMENT

After putting defendants through months of far-reaching discovery, encompassing millions of pages of documents, and more than 100 hours of depositions, one thing is clear: this lawsuit should be dismissed. Although plaintiffs bear the burden of producing evidence as to the elements of their claims, they have no evidence to support their allegation that the defendants – members of Pfizer's board of directors and senior management – consciously disregarded allegations of illegal promotion of Pfizer medicines. Under the governing legal standard, this case is solely about whether defendants, acting in bad faith, consciously disregarded or affirmatively encouraged violations of the law. Seeking to subject directors and officers to personal liability for the conduct of employees – the only possible theory of liability in this case – is "the most difficult theory in corporation law upon which a plaintiff might hope to win a judgment." See In re Caremark Int'l Inc. Deriv. Litig., 698 A.2d 959, 957 (Del. Ch. 1996) (adopted by the Delaware Supreme Court in Stone ex rel. AmSouth Bancorp. v. Ritter, 911 A.2d

[1] Although currently a named defendant, Frank A. D'Amelio is not listed on this motion because plaintiffs have informed counsel for Mr. D'Amelio that they will be dismissing him from the litigation.

362 (Del. 2006). As a matter of law, plaintiffs cannot meet this high standard because there is no evidence that the director and officer defendants violated their respective duties of loyalty. Plaintiffs do not and cannot present evidence that defendants learned of illegal conduct and, in bad faith, consciously disregarded it. Plaintiffs do not and cannot present evidence that defendants, acting in bad faith, knowingly caused any violations to occur.

Although not material to the point – which is dispositive – that plaintiffs lack the evidence required to meet the applicable legal standard, there is ample evidence in the record that the board and management defendants actively discouraged violations of healthcare law and related company policies. The board and management defendants implemented extensive healthcare compliance polices and procedures; regularly reviewed the functioning of the compliance program; repeatedly emphasized the importance of compliance; devoted literally hundreds of millions of dollars in resources to healthcare compliance; investigated thoroughly with outside counsel alleged violations of law or company policies; reported matters candidly to the regulators; implemented remedial measures when issues arose; and directed disciplinary actions be taken wherever appropriate.

In the face of these facts, plaintiffs did not focus their discovery with an eye on the legal principles and factual issues governing their claims. Plaintiffs instead have pursued this case as if defendants owed a duty to prevent illegal conduct by Pfizer personnel, and that the existence of such conduct in itself establishes liability. This is not, however, a case about whether Pfizer violated the law. Pfizer is only a nominal party. It is about whether individual members of the board and senior management personally breached any duties. Defendants have no duty – under law or contract – to succeed in preventing violations of law. For good reason, Delaware law does not impose such an obligation. See, e.g., Stone v. Ritter, 911 A.2d 362, 373 (Del. 2006)

(noting that directors are not expected to "invariably prevent employees from violating criminal laws, or from causing the corporation to incur significant financial liability").

Conceding that the law does not impose a duty to succeed in preventing illegal conduct, plaintiffs misled this Court on the motion to dismiss, into believing that the Corporate Integrity Agreements ("Corporate Integrity Agreements" or "CIAs") Pfizer entered into with the government in 2002 and 2004 required the board of directors to actually "prevent" illegal conduct. The CIAs impose no such obligation. Had they, the government certainly would have charged Pfizer with a breach of those agreements. The government, however, has never suggested a breach of either Corporate Integrity Agreement. Indeed, the Independent Review Organization charged with monitoring Pfizer's performance under the 2004 CIA filed yearly reports through 2009 certifying that Pfizer was in full compliance with its terms.

Unable to come forward with evidence of conscious disregard, let alone bad faith, as necessary to meet the exacting legal standard that governs this case, plaintiffs instead hope to proceed as though this is a negligence or strict liability case. They have adopted the untenable theory that no matter what Pfizer's board and senior management did, if non-compliant conduct occurred, defendants should have done more to prevent it. That is not the law. The duty that Delaware law does impose on directors and officers is to design, in the exercise of their business judgment, reporting procedures intended to keep them informed of company conduct and to not consciously disregard or affirmatively encourage violations of law. There cannot be any genuine dispute that defendants clearly exceeded that standard.

Just as plaintiffs cannot prove their claims by relying on the mere fact that illegal conduct occurred, so too plaintiffs cannot meet their evidentiary burden by disputing the adequacy or timeliness of defendants' responses to alleged misconduct. In the absence of evidence of a bad

faith failure to take action, defendants' decisions as to how to respond to alleged misconduct are protected by the business judgment rule. Plaintiffs' claims also cannot survive summary judgment for the separate and independent reason that they are barred by the three-year statute of limitations. For these reasons, defendants are entitled to summary judgment as a matter of law.

STATEMENT OF UNDISPUTED FACTS

The undisputed facts in this case demonstrate that every time an allegation of improper conduct (a so-called "red flag") came to the board or management's attention, defendants addressed the issue. The consistent approach adopted by the directors and officers was to investigate the issue, stop the conduct from continuing, discipline those involved, deter a recurrence of improper conduct and disclose the matter to the government. During the discovery phase, plaintiffs completely ignored the steps defendants took to address the alleged red flags. Instead, plaintiffs mischaracterize several government resolutions to suggest that Pfizer is a recidivist even though, other than the Bextra resolution, the criminal resolutions involved illegal conduct by companies before they were acquired by Pfizer.[2] Plaintiffs similarly ignore that the alleged red flags involved legacy conduct on the part of predecessor companies with respect to Lipitor, Neurontin and Genotropin, and alleged conduct on the part of non-management Pfizer personnel with respect to Bextra, Geodon, Lyrica and Zyvox. With respect to Bextra, the lead prosecutor in the investigation, Assistant U.S. Attorney Sara Bloom, recently stated that the conduct involved "nuanced behavior" that – when prosecutors learned of the allegations in 2004 – was considered at that time to be "too close" for criminal prosecution. (Defs.' Statement of Undisputed Material Facts Pursuant to Local Rule 56.1 (hereinafter "Defs.' 56.1 Statement") ¶

[2] Moreover, plaintiffs mischaracterize the $2.3 billion resolution with the government to suggest the company pled guilty to conduct beyond that regarding Bextra. In fact, the Bextra plea was the only criminal plea, the resolution with respect to the other medications was a civil settlement and Pfizer expressly denied the government's allegations.

20 (article discussing the evolution of prosecutors' theories regarding what constitutes off-label promotion).) Plaintiffs indiscriminately lump together various practices involved in those matters and assert that such practices constitute "off-label promotion," even though no statute or case law has ever made illegal any purported form of off-label promotion other than the making of a claim of safety or effectiveness to a physician for an off-label use.[3]

A. The Board of Directors and Senior Management

The Pfizer board has always featured a diverse group of highly-credentialed directors, purposefully constructed to have relevant experience and expertise in all of the areas critical to a major pharmaceutical company, including (i) medicine, (ii) science, (iii) education, (iv) research, (v) law, (vi) finance, and (vii) technology. Each of the board members is independent of company management, except for the current and former CEO. (Id. ¶ 1.) The distinguished members of Pfizer's board who are defendants include a Nobel Laureate in the field of Physiology or Medicine; a Harvard Medical School professor and Chief of Medicine at Massachusetts General Hospital; a board member of New York University Medical Center and Memorial Sloan-Kettering Cancer Center; current and former presidents or chairpersons of prominent colleges and universities; a former Deputy Secretary of the United States Department of Health and Human Services; a former Chairman of the United States House of Representatives' Budget Committee and Majority Whip, numerous former Chairmen and Chief Executive Officers, and two graduates of the Harvard Law School, one of whom (Chairman and

[3] As but one example, plaintiffs suggest that the making of comparative claims regarding certain medical properties of FDA-approved medications, even where those properties are set forth in the FDA-approved labels for the products, is illegal. Such conduct, which formed the bases of the Lyrica and Zyvox matters described herein, does not constitute off-label promotion or otherwise violate the misbranding provisions of the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 01, et. seq., and no court has held to the contrary. Accordingly, reports relating to such conduct do not necessarily suggest the possibility of off-label promotion.

CEO, Jeffrey B. Kindler) clerked on the United States Supreme Court and the other on the United States Court of Appeals for the Fourth Circuit. (Id. ¶ 2.)

Pfizer's senior management, who are defendants, also bring to bear rich backgrounds in business, law, science and medicine. Mr. Kindler joined Pfizer in 2002 as General Counsel and Chief Compliance Officer, and was named CEO in 2006. (Id. ¶ 3.) Mr. Kindler came from a compliance background, having been a Vice-President of Litigation and Legal Policy at General Electric. (Id. ¶ 4.) Douglas M. Lankler is a former Assistant United States Attorney in the Southern District of New York. Mr. Lankler, who Mr. Kindler promoted to Deputy Compliance Officer in 2002, became Chief Compliance Officer when Mr. Kindler became CEO in 2006. (Id. ¶¶ 5-7.) Dr. Joseph M. Feczko is an experienced physician and scientist who brought his understanding of clinical research and medical safety issues to the position of Chief Medical Officer, a position created by Mr. Kindler when he became CEO. (Id. ¶¶ 8-9.) Ian Read joined Pfizer in 1978 and became President of Worldwide Pharmaceuticals Operations in mid 2006, after having served in operations for Europe, Canada, Latin America and Africa/Middle East. (Id. ¶ 10.)

The board and management engaged in frequent, regularized discussions and communications related to healthcare compliance. (Id. ¶ 11.) The audit committee, which is tasked with compliance oversight, typically met 10-12 times a year during the relevant period. (Id. ¶¶ 12-13.) At nearly every meeting, the committee heard from the Chief Compliance Officer (COO), Chief Financial Officer (CFO), external auditor (KPMG) and/or internal auditors on compliance matters, and annually the September meeting was dedicated to compliance. (Id. ¶¶ 14.) At least a week before a meeting, committee members received – and then devoted time reviewing – detailed "pre-read" reports from management covering a range of compliance activities and areas of emerging regulatory interest, thereby allowing the committee members to

prepare for and engage management in robust discussions. (Id. ¶ 15.) In addition, the audit committee insisted that the CCO annually certify that the compliance group had adequate resources and access to the board and management and otherwise keep it updated on the operations and effectiveness of the compliance program. (Id. ¶ 16.) The audit committee also was advised promptly of compliance matters warranting investigations, including qui tam actions, and required that it be regularly provided with a "tracking chart" to monitor the progress of these matters. (Id. ¶ 17 (example of the matters tracking report).)[4] In addressing matters under investigation, the committee involved itself in ongoing discussions with management on implementing corrective measures, disciplining employees who were found to engage in non-compliant conduct, and cooperating with regulators as information came to light. (Id. ¶ 18.) In turn, the audit committee, often with the involvement of management, apprised the full board at each board meeting of any notable compliance matters, including enhancements to compliance programs, investigations, remedial steps and disciplinary measures. (Id. ¶ 19.)

B. Defendants' Responses to Alleged Red Flags and Compliance Efforts After the Acquisition of Warner-Lambert in June 2000

Plaintiffs have focused heavily on the Neurontin plea as an example of a red flag, but as is the case with all of the so-called red flags cited by plaintiffs, they have not made any mention of the efforts defendants undertook both before and after that plea to discourage illegal promotion of Neurontin and other products. Beginning in June 2000, when Pfizer acquired Warner-Lambert, and with it, Neurontin, the board received status reports from management that the government's investigation of pre-acquisition promotional practices by Warner-Lambert

[4] Pfizer's outside auditor, John Chapman of KPMG, a self-described "skeptic," testified that senior management was "forthcoming," "transparen[t]," and "diligen[t]" in addressing compliance matters, and that the audit committee "was extremely engaged and very . . . demanding," and that the Company provided an "open check" book to continuously enhance its compliance program. (Id. ¶ 18.)

employees did not implicate any Pfizer activities. (Id. ¶¶ 21-22, 26.) Even though the allegations did not touch Pfizer, the company nevertheless took prophylactic steps to deter the type of conduct that was the subject of the preexisting government investigation. For example, the President of the Worldwide Pharmaceutical Organization, Karen Katen, who reported directly to then-CEO Dr. Henry A. McKinnell, directed that certain policies be adopted to discourage any off-label promotion of Neurontin for uses unrelated to epilepsy.[5] (Id. ¶ 27.) These policies included, (i) limiting the detailing of Neurontin to a small sales force of only 150 representatives who would call only on neurologists; (ii) giving sales credit to representatives only for prescriptions written by neurologists and epilepsy centers; (iii) limiting speaker programs to the approved epilepsy indication; and (iv) eliminating entirely the Warner-Lambert Medical Liaison function that was at the heart of the alleged off-label promotion investigation by the Boston U.S. Attorney's Office. (Id. ¶ 25, 27.) The effectiveness of those measures is graphically demonstrated by DOJ's acknowledgment that Pfizer had not engaged in any illegal conduct, even though the company continued to promote Neurontin for nearly four years after the acquisition of Warner-Lambert in 2000. (Id. ¶ 28 (statement in Neurontin plea agreement recognizing conduct stopped when Pfizer acquired Warner-Lambert).)

Motivated in part by the Neurontin experience, then-CEO McKinnell, hired Jeffrey B. Kindler because he was "the very best general counsel [he] could find with the very best background in not only the corporate legal environment of the legal department but very specifically on compliance." (Id. ¶¶ 29-30.) Among Mr. Kindler's first actions as General

[5] At the time of the Warner-Lambert acquisition, Neurontin was indicated only for the treatment of epileptic seizures. (Id. ¶ 23.) The ongoing government investigation was focused on the use of Warner-Lambert's Medical Liaisons to promote Neurontin for pain and psychiatric uses. (Id. ¶ 25.) Notably, after Pfizer' acquisition of Warner-Lambert, Pfizer sought and obtained approval of Neurontin for postherpetic neuralgia, a type of neuropathic pain. (Id. ¶ 24.)

Counsel and Chief Compliance Officer was revising Pfizer's policies and procedures regarding promotion and significantly investing in the training of employees on these policies and procedures. (Id. ¶ 31 (memo to board discussing creation of policy guides focused on particular job functions and significant investment in compliance training).) This included a $16.8 million investment in a Pfizer Compliance Training Center that required employees to pass a test documenting their knowledge of company compliance policies and procedures. (Id. ¶ 32.) To further encourage employee reporting of compliance-related issues, Pfizer re-launched its Global Alert Hotline in 35 languages enabling employees to file complaints with the compliance group. (Id. ¶ 33.)

In 2002, Pfizer settled civil claims under the False Claims Act alleging that a subsidiary of Warner-Lambert paid a pharmacy benefit manager to place Lipitor on preferred status, allegedly allowing Warner-Lambert to avoid paying Medicaid rebates based upon Lipitor's "best price." (Id. ¶ 35.) All alleged conduct occurred before Pfizer's acquisition of Warner-Lambert. In re Pfizer Inc. S'holder Derivative Litig., No. 09 Civ. 7822, slip op. at 3 (S.D.N.Y. July 14, 2010). (See also Defs.' 56.1 Statement ¶ 36.) The resolution resulted in a $49 million civil settlement payment[6] by Pfizer in exchange for a release from certain liability from the government, as well as an agreement by Pfizer to enter into a Corporate Integrity Agreement with the Office of Inspector General of the Department of Health and Human Services ("HHS OIG"), concerning compliance with Medicare and Medicaid pricing requirements. (Defs.' 56.1 Statement ¶ 37 (Lipitor Corporate Integrity Agreement ("2002 CIA")).)

[6] Plaintiffs repeatedly mischaracterize this and other civil settlements of claims under the False Claims Act ("FCA"), 31 U.S.C. §3729, et seq., as "fines" or "penalties." The FCA provides for civil damages, and these resolutions involved settlements rather than "penalties" or "fines" as plaintiffs suggest in their complaint. Although, the statute also has a criminal component, those provisions have never been invoked in connection with any of the prosecutions and civil settlements at issue in this litigation.

Significantly, the Lipitor settlement and the 2002 CIA did not relate to off-label promotion. (Id. ¶¶ 38-39.) During the term of the 2002 CIA, the government never alleged a single breach of that agreement. (Id. ¶ 41.) Moreover, despite the fact that Warner-Lambert and Pfizer jointly promoted the product, the underlying conduct involved related to Warner-Lambert personnel as distinct from Pfizer's; Pfizer personnel did not engage in the misconduct. (Id. ¶ 34.) The 2002 CIA essentially codified Pfizer's existing compliance policies, which, by implication, reveals that the government had confidence in Pfizer's systems and wanted them applied to the Warner-Lambert activities. (Id. ¶ 40.)

C. Defendants' Efforts to Discourage Illegal Conduct Prior to and Following the Acquisition of Pharmacia in April 2003

Just as it had done with respect to Neurontin upon the acquisition of Warner-Lambert, prior to and following the acquisition of Pharmacia, the board and management took steps to discourage and address potential off-label promotion of Pharmacia products. In the year prior to the April 2003 acquisition of Pharmacia, Pfizer and Pharmacia co-promoted Bextra. (Id. ¶¶ 42-44.) Both companies expected Bextra to be indicated for the treatment of acute pain generally. (Id. ¶ 45-46.) When the FDA denied approval of that indication, Ms. Katen issued a clear directive to the Bextra sales force, one week prior to the launch of the product, to discourage any promotion of Bextra for acute pain. (Id. ¶¶ 47, 49 ("Indications that are under investigation or which are not FDA approved, such as acute pain, **must not** be discussed." (emphasis in original)).) Ms. Katen re-iterated this message in a presentation she made at the April 2002 Bextra launch meeting. (Id. ¶ 52 (instruction from Pfizer and Pharmacia business leaders regarding need to promote within guidelines).)[7]

[7] In addition to emphasizing the clear message to the field force discouraging the promotion of Bextra for acute pain, it should be noted that all Bextra pre-launch advertising and promotional materials were submitted to FDA for approval as required by law. (Id. ¶ 48.) Pfizer also submitted post-launch

When Pfizer acquired Pharmacia in April 2003, Pfizer learned that Pharmacia had been improperly promoting Genotropin. (Id. ¶ 53.) In response, Mr. Kindler (i) promptly retained outside counsel; (ii) directed that outside counsel investigate the matter promptly; and (iii) voluntarily disclosed the conduct to the DOJ. (Id. ¶ 54-55.) That disclosure was made within 30 days after the acquisition. (Id. ¶ 54.) During the course of the Genotropin investigation, the board and audit committee continued to oversee enhancements in Pfizer's monitoring and enforcement of policies prohibiting off-label marketing. (Id. ¶ 56.)

Pharmacia subsequently entered into a deferred prosecution agreement relating to the alleged off-label promotion of Genotropin. (Id. ¶ 57.) Pharmacia also agreed to plead guilty to offering an illegal kickback to a pharmacy benefit manager to obtain improved positioning for the drug Genotropin and paid a total of $34 million to resolve these matters. (Id. ¶¶ 58-59.)[8] Both of these resolutions involved conduct prior to Pfizer's acquisition of Pharmacia. (Id. ¶ 53.) Plaintiffs incorrectly imply that the conduct occurred after Pfizer's acquisition of Pharmacia, Compl. ¶ 9, 105, in order to further their efforts to mischaracterize Pfizer as a recidivist.[9]

In addition to "act[ing] responsibly" with respect to Genotropin, Pfizer continued to guard against the off-label promotion of Bextra. (Defs.' 56.1 Statement ¶ 55.) For example, upon learning in June 2003 that certain members of the sales force were distributing potentially off-label surgical protocols and hospital standing orders relating to the use of Bextra, management promptly issued a "cease and desist" order to the sales force reiterating prohibitions

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materials for FDA review and, notably, FDA never issued a notice of violation or warning letter with respect to such materials. (Id. ¶¶ 50-51.)

[8] The Federal Anti-Kickback Statute ("AKS") makes it illegal to knowingly and willfully pay, solicit or receive any remuneration, directly or indirectly, in return for furnishing or arranging for any health care services for which payment may be made by a Federal health care program. 42 U.S.C. § 1320a-7b(b).

[9] It also bears noting that Pfizer has never been found to have paid an illegal kickback.

on messaging. (Id. ¶ 60.) This was followed by a "Do's and Don'ts" workshop in November 2003 for sales managers. Among the "Don'ts" addressed in the workshops were promoting Bextra for acute pain and providing 20 mg samples for uses other than primary dysmenorrhea. (Id. ¶ 61.) These proactive steps were taken prior to February 2004, when the government disclosed to Pfizer the existence of a qui tam complaint making allegations regarding off-label promotion of Bextra. (Id. ¶ 62.)

D. Disclosure of the Bextra Qui Tam and Entry into the 2004 CIA (February 2004-May 2004)

During negotiations of the Neurontin resolution, Pfizer learned for the first time of the existence of the Bextra qui tam and its allegations in February 2004. (Id. ¶¶ 62-63.) Primarily the allegations in the qui tam related to issues of off-label promotion: the distribution of allegedly off-label protocols and standing orders; providing 20 mg samples for use in treating arthritis pain despite the approved dosage for that use being only 10 mg; and sales force detailing for acute pain. (Id. ¶ 65.) In response, Pfizer retained an outside law firm to perform an investigation and agreed to report its findings to the government. (Id. ¶ 66.) The board was promptly advised of the existence of the qui tam within the very month the government disclosed the qui tam's existence, and the board advised and directed immediate inquiry and corrective steps. (Id. ¶ 67.)

Following the disclosure of the Bextra qui tam, Pfizer entered into the Neurontin resolution in May 2004. (Id. ¶ 68.)[10] As with Lipitor and Genotropin, none of the conduct at

[10] Warner-Lambert admitted to certain, specific instances of off-label promotion of Neurontin that violated the misbranding provisions of the FDCA. (Id. ¶ 69.) Contrary to the plaintiffs' allegations, Compl. ¶ 98, Warner-Lambert was not charged with, and did not admit, or plead guilty to, fraud. (Defs.' 56.1 Statement ¶ 70 (charges forming basis of guilty plea consist of "distribution of an unapproved new drug and distribution of a misbranded drug").) Pfizer paid a $240 million criminal fine and entered into a civil settlement with a $190 million payment in exchange for a release from liability under the False Claims Act. (Id. ¶ 71.)

issue occurred after Pfizer's acquisition of Warner-Lambert. (Id. ¶ 72.) In fact, Pfizer promoted Neurontin for over four years after it acquired Warner-Lambert yet the government found no basis for a claim against Pfizer. As part of the Neurontin resolution, Pfizer entered into another corporate integrity agreement that largely memorialized Pfizer's then-existing compliance practices. (Id. ¶ 73 (Neurontin Corporate Integrity Agreement ("2004 CIA")) ("Pfizer shall continue the operation of its compliance measures in accordance with the terms [of the 2004 CIA]") (emphasis added).)[11]

At the time the 2004 CIA was entered into, the government already was aware of the allegations concerning the promotion of Bextra and had brought the Bextra qui tam to Pfizer's attention two months earlier.[12] (Id. ¶ 75.) Indeed, the same government lawyers involved in the negotiations of the 2004 CIA disclosed the qui tam to Pfizer. (Id. ¶¶ 64, 76.) The government was able to and did dictate to the company any provisions it thought were necessary to include in the 2004 CIA as a result of the allegations in the Bextra qui tam. The government nevertheless imposed few (if any) new obligations on Pfizer in the 2004 CIA, in recognition of the company's pre-existing procedures. (Id. ¶ 77.)

Pfizer operated under the 2004 CIA from May 11, 2004 through May 11, 2009. (Id. ¶ 78.) During its five-year term, the Independent Review Organization ("IRO")[13] appointed to

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[11] In particular, the 2004 CIA stated that Pfizer "presently has" and "shall continue to employ" a Compliance Officer, that Pfizer "makes and shall continue to make the promotion of [its Code of Conduct] an element in evaluating the performance of all employees," that Pfizer's "Policies and Procedures address and shall continue to address" the issues in the 2004 CIA, that staff "were and shall continue to be available to explain the Policies and Procedures," and that Pfizer "shall continue to publicize the existence of [its] disclosure mechanism." (Id. ¶ 74.)

[12] The Bextra Information and plea agreement contain no allegations of any specific misconduct after receipt of the Bextra qui tam in February 2004. Indeed, every reference to specific misconduct in the Bextra Information is to conduct that occurred in 2002 or 2003.

[13] PricewaterhouseCoopers served as the Independent Review Organization. (Id. ¶ 79.)

monitor Pfizer's compliance with the agreement never found that the company breached the CIA. (Id. ¶ 80.) Nor did HHS OIG – which, pursuant to the 2004 CIA, received annual reports from both the company and IRO and conducted its own site inspections – ever suggest any breach of the 2004 CIA.[14] (Id. ¶¶ 81-82.)

Contrary to the allegations in the plaintiffs' complaint, neither the 2004 CIA nor the earlier 2002 CIA imposed upon Pfizer's directors or officers the obligation to succeed in preventing violations of the law. See, e.g., Compl. ¶ 101; see also Transcript of Oral Argument at 22:17-23:14, 35:14-36:5. The complaint's repeated misinterpretation of the terms of the 2002 and 2004 CIAs resulted in the Court incorrectly postulating that the agreements imposed duties upon defendants greater than those required under Delaware law. See In re Pfizer Inc. S'holder Derivative Litig., No. 09 Civ. 7822, slip op. at 16. That is simply not true. In fact, neither agreement, nor any law or regulation, obligates Pfizer's directors and officers to prevent violations of law.

E. Responding to the Allegations in the Bextra Qui Tam (May 2004-April 2005)

In addition to the numerous steps taken in 2002 and 2003 to discourage off-label promotion, upon learning of the Bextra qui tam Pfizer acted to address the conduct alleged in the complaint. Without waiting for the results of the investigation by outside counsel of the Bextra qui tam allegations and despite not having determined as of that date whether there was merit to the allegations, in May 2004, the head of sales sent a communication to the entire Bextra sales force addressing the conduct alleged in the qui tam complaint. (Defs.' 56.1 Statement ¶ 84). The communication reminded those involved in the promotion of Bextra that they were not permitted to: (i) promote Bextra for acute pain unconnected to osteoarthritis or rheumatoid

[14] HHS OIG was involved in the investigation and settlement discussions. (Id. ¶ 83.)

arthritis; (ii) make unapproved comparisons between Bextra and Vioxx; or (iii) create off-label protocols or standing orders. (Id.).

The message to the field force was reinforced in the summer of 2004 through a comprehensive meeting with, and re-training of, the sales force. (Id. ¶ 85 (presentation addressing each of the issues identified in Bextra investigation).) This re-training also reiterated that the distribution of 20 mg samples be limited to physicians treating primary dysmenorrhea (an approved indication). (Id.) In August 2004, this direction was reinforced by restricting the availability of 20 mg samples to only those sales representatives calling on physicians who treat primary dysmenorrhea, and reducing the number of samples distributed to an amount consistent with primary dysmenorrhea use. (Id. ¶ 86.) In September 2004, district managers were directed to review physician recall data for any signs of off-label marketing. (Id. ¶ 87 (instructing managers to review reports for any indications that messaging may be inconsistent with company policy).)[15] And in October 2004, the company issued an additional reminder not to promote Bextra for acute pain in the wake of the withdrawal of Vioxx. (Id. ¶ 89 (reminding sales colleagues that Bextra could not be promoted as a replacement for Vioxx because of the difference in their approved indications).)

In addition to the efforts directed at Bextra specifically, the then-current audit committee members of the board of directors, along with the participation of Mr. Kindler and Mr. Lankler, began a review in 2004 of the policies and procedures around promotional efforts that are used across many products. (Id. ¶ 90.) One area of focus was the manner in which speaker programs (a usual industry practice involving the payment of fees to physicians who can share appropriate insights and information in a monitored setting with other physicians) were conducted and

[15] The company took this step despite the fact that physician recall statements are notoriously unreliable. (Id. ¶ 88.)

speakers were compensated. (Id. ¶ 91 (audit committee presentation regarding proposed enhancements sought by defendants to speaker program policies and procedures); id. ¶ 92.) In order to actively discourage either the possibility or perception of kickbacks, in 2005, payments to speakers were tied to fair market value for the speaker's time and an annual cap on honoraria for each speaker was imposed. (Id. ¶ 93 (memo documenting that enhancements requested by defendants were adopted).) To discourage the possibility of off-label discussion at speaker programs, speakers were also required to undergo compliance training, and permitted to use only Pfizer-approved slide decks. (Id. ¶ 94.) Also in 2005, as a result of the Audit Committee's initiative to evaluate the policies and procedures applicable to drug-related promotional efforts, honoraria for physician mentorships were discontinued. (Id. ¶ 95.)

In April 2005, Pfizer, in consultation with FDA, voluntarily withdrew Bextra. (Id. ¶ 96.) The decision to withdraw Bextra was based on data regarding Stephens Johnson Syndrome adverse events, a rare condition specifically referenced in the Bextra label. (Id. ¶ 97.) The withdrawal had nothing to do with the government's allegations of off-label promotion. (Id.)

F. The Bextra Resolution

To resolve the Bextra investigation, Pfizer ultimately agreed to plead guilty to one count of off-label promotion of Bextra and pay a criminal fine of $1.3 billion. (Id. ¶ 98.) In addition to the Bextra plea, Pfizer paid $1 billion to settle civil False Claims Act allegations relating to Bextra and other drugs. (Id. ¶ 99.)[16] Contrary to plaintiffs' allegations, while Pfizer admitted that there was a factual basis for its plea, it did not admit to the government's description of the underlying misconduct contained in the Information or described by the prosecutor at the plea

[16] Plaintiffs incorrectly characterize the civil settlement as a "punishment" and the settlement payment as a penalty. (Compl. ¶ 142)

allocution. (Id. ¶ 100 (stating disagreement with certain of government's allegations, but acknowledging existence of a factual basis for a plea).)

In fact, Pfizer disagreed with the government's assessment of the facts and the law, but did not believe it could risk a fight with the government as long as the possibility of permissive debarment that accompanies an indictment existed. (Id. ¶ 101.) If Pfizer did not reach a voluntary resolution with the government of the ongoing investigations of Bextra marketing practices, the company faced the risk of debarment from participation in federally-sponsored/financed health care programs (i.e., Medicare and Medicaid). (Id. ¶ 102.) Pfizer urged the government to allow Pfizer to litigate the merits of the government's claims without the risk of full debarment, but the government refused to do so. (Id. ¶ 103 (letter from Pfizer outside counsel expressing the company's interest in trying the case).) The risk of exclusion presents potentially severe economic effects for a major pharmaceutical company such as Pfizer, and that risk provides the government enormous leverage in negotiating the basis and terms of a settlement agreement. (Id. ¶ 105.) Pfizer is not alone. Almost every other major pharmaceutical company has faced a similar risk and ultimately entered into a settlement in which it paid a large sum of money and entered into a Corporate Integrity Agreement, including, but not limited to: Johnson & Johnson; Roche; GlaxoSmithKline; Novartis; Sanofi-Aventis; AstraZeneca; Abbott Laboratories; Merck; Bayer; Eli Lilly; Bristol-Myers Squibb; and Allergan Inc. (Id. ¶ 106.) Many of these companies, like Pfizer, pled guilty to similar allegations concerning sales and marketing promotional activities. (Id. ¶ 107.) Pfizer, like each of the companies listed above, settled on the best possible terms that it could negotiate with the government. (Id. ¶ 108.)

As part of the resolution, Pfizer also agreed to enter into a new five-year CIA that was the product of months of negotiation between Pfizer and the government. (Id. ¶ 109.) This CIA made three additions to Pfizer's existing compliance program. Those additions were to require

that the Chief Compliance Officer report directly to the Chief Executive Officer, that Pfizer publicly disclose health-care provider payments, and that the audit committee adopt and submit an annual resolution stating that the audit committee has made a reasonable inquiry into the operations of Pfizer's Compliance Program and that Pfizer has implemented an effective Compliance Program. (Id. ¶ 110.)

Notably, there is no conceivable basis for asserting that any off-label promotion of Bextra occurred after April 2005, when the product was withdrawn from the market (for reasons unrelated to the government's allegations of off-label promotion). In fact, it is significant that the Information and plea agreement contain no specific allegations of any misconduct after receipt of the Bextra qui tam in February 2004. (Id. ¶ 111.) Every reference to specific conduct in the Bextra Information is to conduct that occurred in 2002 or 2003, before Pfizer learned of the qui tam lawsuit and took the steps outlined above, and before Pfizer entered into the 2004 CIA. (Id. ¶ 112).[17]

G. Defendants' Ongoing Efforts to Discourage Illegal Conduct and Respond to Allegations of Off-Label Promotion (April 2005-Present)

Confronted with the undisputed facts that there could not have been any Bextra misconduct after Bextra was voluntarily removed from the market in April 2005 and that the Criminal Information contained no specific allegation that occurred after the government's

[17] Prior to the time the government disclosed the existence of the Bextra qui tam to defendants, the Congress of California Seniors in December 2002 filed a lawsuit in California alleging that Pfizer and Pharmacia had paid to have a study on the use of Bextra for dental pain published in a dental journal. (Id. ¶ 113.) The Congress of California Seniors is an interest group with the express purpose of acting as a vehicle for bringing litigation against the pharmaceutical industry. (Id. ¶ 114 (article discussing the organization as a vehicle for class action plaintiffs).) Pfizer retained an outside law firm to review the allegations and handle the litigation. (Id. ¶ 115.) The complaint did not allege any conduct of the sort that became the focus of the government investigation; rather, the complaint focused exclusively on the publication of a single article in a medical journal. (Id. ¶ 116.) No court has ever held that the publication in a medical journal of an article discussing an off-label use violates the FDCA. The case was subsequently dismissed in December 2004. (Id. ¶ 117.)

disclosure of the Bextra-related qui tam in 2004, plaintiffs attempt to create an impression of ongoing alleged misconduct by referencing subsequent investigations of other Pfizer medicines. In each case, however, the undisputed facts demonstrate that Pfizer sought to discourage off-label promotion prior to any investigation by the government related to off-label promotion and respond to issues raised by any alleged red flags regarding these products.

Shortly after the withdrawal of Bextra in April 2005, Pfizer began preparations for the launch of Lyrica, a product that was in the same therapeutic class and shared two FDA-approved indications with Neurontin. (Id. ¶¶ 118-120.) In preparation for the September 2005 launch of Lyrica and prior to any government inquiry or qui tam lawsuit, Mr. Kindler, Mr. Lankler, and other Pfizer legal, compliance and business personnel, took a number of steps to discourage off-label promotion of Lyrica, including prohibiting sales representatives' from detailing psychiatrists because Lyrica was not approved for any psychiatric use at the time. (Id. ¶¶ 121-122 (outlining measures adopted by defendants to discourage off-label promotion of Lyrica).) Psychiatrists were excluded from sampling, and their prescriptions were not counted for either sales quota or credit. (Id. ¶ 123.) The company also adopted measures specific to orthopedists and rheumatologists - specialties that use the product on-label, but also might prescribe it off-label - including (i) limiting samples to reflect what the company believed to be the on-label use by these specialists; (ii) reducing the percentage of compensation based on Lyrica for sales representatives calling on these specialists; and (iii) counting only a percentage equal to the specialties' believed on-label use toward sales representatives' sales credit and quota ("factoring"). (Id. ¶ 124.) More broadly, sales quotas were calculated to eliminate sales that the company estimated to be attributable to off-label prescriptions. (Id. ¶ 125.) Senior business and legal personnel also delivered to the entire field force responsible for promoting Lyrica a

presentation at the product launch on the need to promote only within the labeled indications. (Id. ¶ 126.)

Despite these precautions, in the fall of 2006, Pfizer received a report from a sales representative that an approved detail aid was being misused in the field. (Id. ¶ 127.) A thorough investigation was conducted by counsel, and the detail piece was withdrawn. (Id. ¶ 128.) Remedial actions were taken, including (i) specific corrective messaging in the districts where detailing pieces were found to have been misused in the field, and (ii) a field force-wide communication from the Senior Vice President of Sales reinforcing the appropriate and permissible promotional messages. (Id. ¶ 129.) These communications were reinforced by a presentation to the sales force in late 2006. (Id. ¶ 130 (training provided to all Lyrica sales representatives regarding importance of staying on label).) These findings were voluntarily self-reported by Pfizer to FDA and prosecutors in November 2006. (Id. ¶ 131.) All of the foregoing occurred before the government initiated an investigation related to Lyrica in July 2007. (Id. ¶ 132 Lyrica subpoena).)

At roughly the same time – in September 2006 – and also prior to any government investigation, a sales representative reported to the compliance group through Pfizer's reporting system that a small group of physicians who were frequently used as Geodon speakers had discussed their own clinical experience treating children and adolescents with Geodon and at dosages higher than those approved by the product's label. (Id. ¶ 133.) Pfizer promptly retained outside counsel to perform a thorough investigation of this allegation. (Id. ¶ 134 (memo outlining comprehensive investigation).) The investigation determined that the conduct had been stopped in 2005 by the speaker program reforms instituted by the company that year at the behest of the audit committee. (Id. ¶ 137.) Nonetheless, additional guidance was provided to the sales force to reiterate that the promotion of Geodon was to be limited to use for adult patients, and

outside medical speakers were retrained on Pfizer policies regarding speaker programs. (Id. ¶ 138.) In addition, to discourage promotion for use by children, the company removed psychiatrists who treat children and adolescents from the calculation used to determine sales force compensation. (Id. ¶ 139.) Pfizer also self-reported these allegations in September 2006, and updated the government throughout the course of the investigation. (Id. ¶ 136.) It was not until December 2007 that the government commenced an investigation relating to Geodon. (Id. ¶ 141.)

In December 2007, Pfizer was informed by DOJ that it believed Pfizer sales representatives were making inappropriate comparative claims regarding Zyvox and vancomyacin. (Id. ¶ 142.) Pfizer had received an FDA Warning Letter in July 2005 that concerned the use of a retrospective analysis of Zyvox data to make a comparative claim with respect to vancomyacin in a journal advertisement.[18] (Id. ¶ 143.) The company disagreed with FDA's view, but promptly withdrew the journal advertisement and ran a corrective advertisement. (Id. ¶ 144.) Pfizer also revised promotional pieces and instructed the field force to discontinue use of the withdrawn pieces. (Id. ¶ 145.) Immediately upon learning of the government's concerns in 2007, Pfizer conducted a comprehensive investigation. (Id. ¶ 146 (describing extensive Zyvox investigation).) The investigation was completed on an expedited basis, and in February 2008 all sales representatives assigned to Zyvox were retrained, in-person, to actively discourage the making of any superiority or off-label claims. (Id. ¶¶ 148-149 retraining provided to all Zyvox sales colleagues).) Additional interviews of sales force were conducted after the retraining to confirm that the re-training on prohibited superiority or off-label

[18] The allegations concerning the making of comparative claims are distinct from the allegations concerning off-label promotion of a drug. Because comparative claims do not implicate usages outside of approved drug usage indications, such claims do not violate off-label promotion laws.

claims were understood by the sales force. (Id. ¶ 150.) The company also provided "in-context" guides to sales representatives to reinforce how detail aides should be properly used and to discourage their misuse. (Id. ¶ 151.) In the wake of this internal investigation, 45 sales colleagues were disciplined for violating Pfizer's policies. (Id. ¶ 152 (setting forth the extensive disciplinary action taken).) This included the termination of the sales manager responsible for anti-infective products. (Id. ¶ 153.)[19]

In addition to the corrective measures addressing specific investigations discussed above, the board of directors and senior management further discouraged inappropriate conduct in other ways. For example, in 2006, Pfizer established the Medical Education Grants Group ("MEG"). (Id. ¶ 154.) MEG was created as a mechanism to prevent the possibility or perception of kickbacks by removing all sales and marketing professionals from the grant process. (Id.) In addition, MEG further sought to ensure that, consistent with company policy, Pfizer marketing personnel have no influence over the content of Continuing Medical Education ("CME") programs that Pfizer funds. (Id.) The involvement of marketing in the publication of clinical studies was also diminished and leadership of that process was placed solely with medical personnel. (Id. ¶ 155.)

Among the actions defendants took in 2007 to discourage off-label promotion, under the leadership of the board and senior management, were the adoption of an enhanced needs assessment process for advisory boards, effectively expanding the approach previously adopted for speaker programs. (Id. ¶ 156.) To ensure that off-label information contained in medical information letters was provided only to physicians who had requested such information, the

[19] As part of the Bextra civil settlement, Pfizer agreed with the United States as to certain specific facts relating solely to Pfizer's marketing of Zyvox (without agreeing that those facts constituted wrongful conduct) but did not admit to any liability. (Id. ¶ 147.)

company also revised those letters to ask physicians receiving the letters to call the company if the physician had not requested the information provided. (Id. ¶ 157.) The company also adopted the Risk Assessment and Mitigation Plan ("RAMP") process to identify compliance risks associated with each promoted product. (Id. ¶ 158.)

Pfizer's efforts to discourage off-label promotion continue to this day. In 2009, defendants, under the leadership of Mr. Kindler, Mr. Read and Mr. Lankler, adopted, among many other modifications, an incentive compensation methodology that attempts to remove the estimated off-label prescription sales from the quota and credit calculations of all products. (Id. ¶ 159 (as explained by Read the data necessary to implement this change across the board for all products only recently became reliable and credible).) In addition, the Promotional Quality Assurance ("PQA") group was established to monitor both the effectiveness of its policies and procedures and detect signs of misconduct. (Id. ¶ 160.)

* * *

As the record makes clear, the board and management worked hand-in-hand to address each of the matters subject to the 2009 resolution with the government. The proof of this is that: (i) the audit committee was immediately apprised by management when the government disclosed either a qui tam complaint and/or initiation of an investigation, and when internal investigations of compliance matters were being conducted, (id. ¶ 161.) (example of disclosure to audit committee of qui tam); (ii) management promptly presented to the committee, for its assessment, how management was investigating – with the use of experienced outside counsel – and remediating the matter, (id. ¶ 162.) (example of report to audit committee detailing investigation); (iii) corrective steps were presented to the board frequently before the investigation was complete, (id. ¶ 163.) (example of report to board of corrective action); and (iv) board members received regular updates on the status of each ongoing investigation,

including the company's efforts at remediation and its cooperation with the government, (id. ¶ 164.) (example of report to board regarding status of ongoing investigation). (See also id. ¶ 169.) Board members also demanded and were provided with information on discipline for any non-compliant conduct identified by these investigations and efforts being made to prevent similar or related conduct. (Id. ¶ 165.) Finally, as the board considered the need to reach a resolution with the government encompassing the open investigations, the compensation committee required a specific presentation to assist its evaluation of any accountability on the part of executive-level personnel currently with the company. (Id. ¶ 166.) Moreover, in response to each of the government investigations on which plaintiffs focus, management also promptly retained experienced, competent outside counsel to investigate thoroughly the underlying allegations. (Id. ¶ 167.) Where any issues were found to exist and without waiting for the full results of the inquiry, management promptly implemented corrective measures. (Id. ¶ 168.)

ARGUMENT

Defendants are entitled to summary judgment "[i]f the undisputed facts reveal that there is an absence of sufficient proof as to any essential element on which the opponent of summary judgment has the burden of proof." Gottlieb v. Cnty. of Orange, 84 F.3d 511, 519 (2d Cir. 1996) (citing, inter alia, Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986)). "[A]ny factual dispute with respect to other elements becomes immaterial and cannot defeat the motion." Id. Once the moving party discharges its initial burden "by . . . 'pointing out to the district court . . . that there is an absence of evidence to support the non-moving party's case," Celotex Corp., 477 U.S. at 325, the burden shifts to the opposing party to come forward with evidence as to each of the essential elements of its claim.

I. Plaintiffs Fail to Raise a Triable Issue of Fact as to Whether Defendants Breached Their Duty of Loyalty.

Under Delaware law,[20] directors and officers owe two separate duties: the duty of loyalty and the duty of care. Stone v. Ritter, 911 A.2d 362, 370 (Del. 2006); see also Gantler v. Stephens, 965 A.2d 695, 708-09 (Del. 2009). Plaintiffs have specifically and repeatedly disclaimed the notion that their claims against defendants are based on an alleged breach of the duty of care. See e.g., Pls.' Mem. Opp'n. at 38, 39, Jan. 8, 2010; id. at 3 ("This is no due care claim."). At issue here is whether defendants breached their duty of loyalty. The amended complaint alleges that the defendants engaged in "conscious and deliberate acts of misconduct." (Pls' Opp., at 23, accord Order at n.3.) Under Delaware law, such intentional or conscious misconduct is recognized as a failure to act in good faith, see In re Walt Disney Co. Derivative Litig., 906 A.2d 27, 67 (Del. 2007), which is a necessary element of a breach of the duty of loyalty claim. See Stone, 911 A.2d at 369-70 ("[T]he fiduciary duty of loyalty . . . encompasses cases where the fiduciary fails to act in good faith."). To hold defendants personally liable for an alleged breach of loyalty, plaintiffs must prove that each defendant acted "intentionally" and in "bad faith." See In re Walt Disney Co., 906 A.2d at 66-67; Stone, 911 A.2d at 370.

The Delaware Supreme Court has pointed to two categories of fiduciary behavior that constitute "bad faith" conduct in breach of the duty of loyalty: (i) where there is an "intentional dereliction of duty" or "a conscious disregard for one's responsibilities," and (ii) where directors act with "subjective bad faith," defined as "conduct motivated by an actual intent to do harm." [Id.] at 64-67; Lyondell Chem. Co. v. Ryan, 970 A.2d 235, 239 (Del. 2009) ("[B]ad faith encompasses not only an intent to do harm but also intentional dereliction of duty."). As

[20] Both sides agree Delaware law applies to the issues in this case. Under the Internal Affairs Doctrine (See Edgar v. MITE Corp., 457 U.S. 624, 645 (1982)), the law of the state of incorporation of Pfizer (Delaware), governs the obligations and responsibilities of officers and directors of the company.

discussed below, under either scenario, plaintiffs must prove – as an essential element of their claim – that defendants acted with knowledge that their action or non-action was wrongful.

The gravamen of plaintiffs' complaint is that defendants consciously disregarded their duties by failing to respond to alleged off-label promotion. Delaware law recognizes a breach of duty of loyalty where "the fiduciary intentionally fails to act in the face of a known duty to act, demonstrating a conscious disregard for his duties." See In re Walt Disney Co. Deriv. Litig., 906 A.2d at 67; Stone, 911 A.2d at 36; see also In re ITT Corp. Derivative Litig., 588 F. Supp. 2d 502, 512-13 (S.D.N.Y. 2008) (dismissing conscious disregard of duty claim because "[t]he complaint [was] devoid of allegations regarding whether or when the information regarding these events or the relevant misconduct was actually presented to the individual Directors and what actions, if any, they took in response"); In re Walt Disney Co. Derivative Litig., 906 A.2d 27, 67 (Del. 2006) (dismissing conscious disregard claim where plaintiffs did not show that "the fiduciary intentionally fail[ed] to act in the face of a known duty to act."). Critical to establishing a conscious disregard claim is "showing that the directors were conscious of the fact that they were not doing their jobs." See In re Citigroup Inc., 964 A.2d 106, 122 n.46 (Del. Ch. 2009) (emphasis added); see also In re ITT Corp., 588 F. Supp. 2d at 508 (indicating that a "scienter-based" standard applies to conscious disregard claims).

The complaint also appears at various points to allege that the defendants actively encouraged off-label promotion and other wrongful conduct in violation of the FDCA, but it is not clear that plaintiffs continue to pursue this claim or that the Court allowed this claim to go forward. Neither the complaint nor the record in this case, however, contains any evidence that any defendant actively encouraged any wrongdoing. To be sure, Delaware does recognize a breach of the duty of loyalty where "the fiduciary acts with the intent to violate applicable positive law." See Stone, 911 A.2d at 369; In re Walt Disney Co., 906 A.2d at 67. To prevail on

such a claim under Delaware law, plaintiffs must show that: (i) each defendant engaged in or encouraged the alleged conduct; (ii) the conduct violated positive law; and (iii) the defendants knew the conduct violated positive law. See Wood v. Baum, 953 A.2d 136, 142 (Del. 2008) (dismissing allegations of illegal conduct where plaintiffs did not plead "the specific conduct in which each defendant 'knowingly' engaged, or that the defendants knew that such conduct was illegal"); In re Walt Disney Co., 906 A.2d at 67 (Del. 2006) (plaintiff must show that the "fiduciary act[ed] with the intent to violate applicable positive law"); Litt v. Wycoff, C.A. No. 19083-NC, 2003 Del. Ch. LEXIS 23 (Del. Ch. Mar. 28, 2003) (dismissing allegations of illegal conduct where "the Complaint fail[ed] to support a reasonable inference that [the conduct] constituted criminal conduct"); Gagliardi v. Trifoods Int'l, 683 A.2d 1049, 1051 (Del. Ch. 1996) (holding bad faith exists when conduct is "known to constitute a violation of applicable positive law").

As set forth below, defendants are entitled to summary judgment as to the sole remaining claims in this case because there is no evidence that they consciously disregarded a known duty to act (let alone that they did so intentionally and in bad faith) or that they actively, intentionally and in bad faith encouraged illegal conduct. The undisputed facts of this case demonstrate that far from consciously disregarding allegations of illegal off-label promotion, the defendants responded to the allegations of illegal conduct and took affirmative steps to stop such conduct. And, rather than encouraging illegal conduct, the defendants took affirmative steps to discourage illegal off-label promotion.

A. There is No Evidence That Defendants Consciously and In Bad Faith Disregarded Alleged Illegal Conduct

Plaintiffs allege that the defendants breached their duty of loyalty to the company by consciously disregarding alleged off-label promotion by Pfizer employees in connection with

several of its products, most notably, Bextra, Zyvox, Lyrica, and Geodon. (Compl. ¶ 211).[21] To survive summary judgment on such a claim, plaintiffs bear the burden of coming forward with evidence showing, among other things, that defendants not only disregarded allegations of off-label promotion but did so consciously and in bad faith. See, e.g., Lyondell, 970 A.2d at 239; Stone, 911 A.2d at 369; In re Citigroup Inc., 964 A.2d at 122 n.46. To be successful on a breach of loyalty claim based upon a defendant's conscious disregard of employees' potential misconduct, plaintiffs must show that defendants "took no steps in an effort to prevent or remedy" violations of the law of which the defendants knew. See In re Abbott Labs. Derivative S'holders Litig., 325 F.3d 795, 809 (7th Cir. 2003) (emphasis added).

It is evident from the extensive discovery in this case that plaintiffs, in opposing this motion, intend to present evidence that illegal conduct occurred and that the steps taken to prevent illegal conduct were not effective. Such a showing would be woefully insufficient. See Stone, 911 A.2d at 373 (noting that directors are not expected to "invariably prevent employees from violating criminal laws, or from causing the corporation to incur significant financial liability"). Plaintiffs incorrectly assert that the 2002 CIA and the 2004 CIA imposed a standard of care on the board of directors other than that imposed by Delaware law. This assertion is incorrect. The CIAs codified Pfizer's existing reporting system but did not impose any additional obligation on the board to act upon reported information other than that required by Delaware law.[22] See (Defs.' 56.1 Statement ¶¶ 40, 77.) In this regard, the CIAs made clear that management was responsible for the day-to-day responsibilities for developing and

[21] Although the complaint contains additional allegations regarding conscious disregard of purported kickbacks, it appears plaintiffs have since abandoned these claims.

[22] Indeed, as noted above, the 2004 CIA was entered into after the filing the Bextra related qui tam, which was based on alleged conduct that occurred in 2002 and 2003.

implementing policies, procedures, and practices designed to operate an effective compliance program and satisfy the requirements of the CIAs. No additional obligations or duties were imposed on the board by the CIAs. Accordingly, the CIAs did not alter defendants' fiduciary duties, nor did they alter the substantive standard of liability for a breach of loyalty.

In a case premised upon conscious disregard, plaintiffs must show that the defendants completely and entirely disregarded "red flags" once they came to their attention; evidence that the response to the "red flags" was inadequate is insufficient. See Lyondell, 970 A.2d at 242-44. As noted in In re Abbott, the bad faith conduct is the board's intentional failure to take any steps to remedy or prevent violations of the law. Id. at 806. Here, plaintiffs cannot prove that the defendants "took no steps" to remedy or prevent violations of law. Rather, the defendants caused many remedial acts to be taken. The fact that later violations may have occurred despite these remedial efforts is not proof of the defendant's bad faith in addressing the "red flags" alleged by the plaintiffs. In re ITT Corp., 588 F. Supp. 2d at 513 ("That [remedial] steps proved to be insufficient to prevent the continuance of criminal conduct does not itself establish conscious disregard of fiduciary duties.").

This distinction was explained by the Supreme Court of Delaware in Lyondell Chemical Company in the context of evaluating director's duties during the sale of a company:

> [T]here are no legally prescribed steps that directors must follow to satisfy their Revlon duties. Thus, the directors' failure to take any specific steps during the sale process could not have demonstrated a conscious disregard of their duties. More importantly, there is a vast difference between an inadequate or flawed effort to carry out fiduciary duties and a conscious disregard for those duties.

Id. at 243-44 (emphasis added). Reversing the trial court's denial of summary judgment and entering judgment for defendants, Delaware's highest court explained that "only if [the director defendants] knowingly and completely failed to undertake their responsibilities would they

breach their duty of loyalty." Id.; (emphasis added); Robotti & Co. v. Liddell, C.A. No. 3128-VCN 2010 Del. Ch. LEXIS 4, at *45 (Del. Ch. Jan. 14, 2010) (dismissing a claim for breach of duty of loyalty and noting "[e]ven if the Defendants did not consider these issues as thoroughly as they should or could have, the alleged facts show that the Defendants did not completely abdicate their fiduciary responsibilities").

Here, as in Lyondell, there are no specifically prescribed steps directors must take when they are made aware of employees' potential wrongdoing. A board's good faith consideration of a "red flag" itself negates any allegation that the board consciously disregarded its duties. Lyondell, 970 A.2d at 243-44; see Robotti & Co., 2010 Del. Ch. LEXIS 4, at *44-45. A court's evaluation of the adequacy of a fiduciary's response to a "red flag" or, indeed, its decision not to respond to "red flags" is actually an inquiry into whether the directors "failed to do all that they should have under the circumstances" – a duty of care inquiry. See Lyondell, 970 A.2d at 243-44. Accordingly, the non-action of a director or officer does not breach the duty of loyalty unless it is shown that the board knew its failure to act was a violation of its duties. See In re Citigroup Inc., 964 A.2d at 128; see also In re ITT Corp., 588 F. Supp. 2d at 508.

Plaintiffs have no evidence that defendants disregarded evidence of wrongdoing when it came to their attention, let alone evidence that such disregard was the product of bad faith. They can point to no document or statement suggesting that defendants knew of, and in bad faith chose to disregard, alleged off-label promotion of any of Pfizer's products, including Bextra, Geodon, Lyrica, or Zyvox. In fact, the undisputed evidence shows that for each of the medications and each of the allegations, when the defendants became aware of potential illegal off-label promotion, they engaged in a good faith effort to investigate and respond to that information. To the extent plaintiffs now wish in hindsight to criticize the adequacy of defendant's response, such an exercise would not satisfy their burden. The question is not whether their response was ideal,

but whether it was undertaken in good faith. See Lyondell, 970 A.2d at 242-44. Thus, plaintiffs cannot survive summary judgment by coming up with additional or different steps defendants might have taken; they must instead proffer evidence of an intentional, bad faith failure to respond in any way to such allegations. Because there is no such proof, plaintiffs cannot satisfy an essential element of their claim, and defendants are entitled to summary judgment as a matter of law.

1. Bextra

Pfizer does not contest that, as admitted in the 2009 plea agreement, there is evidence that certain Pfizer employees engaged in off-label promotion of Bextra prior to the voluntary withdrawal of the product from the market in April 2005. Plaintiffs have not identified any evidence, however, to establish that defendants disregarded such conduct when it came to their attention – much less that they did so intentionally.

The undisputed evidence shows that significantly in advance of the time the government provided Pfizer with a redacted copy of a qui tam complaint alleging off-label promotion of Bextra, the company had already taken numerous steps to prevent the conduct that was alleged in the complaint. For example, at the time of Bextra's launch Pfizer's senior management specifically cautioned sales colleagues against promotion of Bextra for acute pain. (Defs.' 56.1 Statement ¶ 49.) Defendants had also already directed that off-label protocols and standing orders not be distributed, and had required all sales managers to attend work sessions at which directions were given regarding the type of messaging that was permissible (Id. ¶¶ 52, 84, 85.) The fact that, despite these and other efforts, some individuals at some level of the company

promoted Bextra for an off-label use is not evidence of conscious disregard by the directors and officers.[23]

Equally important, plaintiffs have no evidence that defendants disregarded the allegations of the qui tam lawsuit in February 2004.[24] The board was immediately informed – within the month – of the qui tam allegations and management's plans to address the issues raised, including the immediate retention of outside counsel to investigate the matter thoroughly. (Id. ¶¶ 66, 67.) At virtually every audit committee meeting thereafter, the board discussed with management the company's corrective and investigative activities concerning Bextra – which included steps to remediate the very practices that the qui tam alleged. (Id. ¶ 90.) Indeed, the evidence shows that defendants responded in good faith by promptly taking these steps even before the investigations were completed. Specifically, the company issued a memo to the entire sales force addressing the conduct identified by the investigation of the qui tam complaint, and re-trained the sales force on those issues. (Id. ¶¶ 84, 85.) Upon receiving findings from outside counsel, the company also restricted the availability of 20 mg samples of Bextra solely to physicians likely to treat primary dysmenorrhea. (Id. ¶ 86.) The effectiveness of the remedial efforts were monitored, in part, through the review of verbatims. (Id. ¶ 87.) In light of the foregoing undisputed facts, plaintiffs cannot carry their burden of coming forward with facts demonstrating a complete disregard of the alleged illegal conduct.

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[23] It bears noting that the conduct alleged in the qui tam complaint was not clearly a violation of law. Notably, the prosecutor who would eventually prosecute the Bextra off-label claims has stated publicly that they were based on a nuanced and untested theory of liability that, even in the eyes of the government, were not initially viewed as clearly viable. See (Id. ¶ 20.)

[24] Notably, none of the specific allegations of off-label promotion of Bextra contained in the Information occurred after Pfizer received the qui tam in 2004. Rather, all of these allegations relate to conduct that occurred in 2002 or 2003, before Pfizer learned of the qui tam and before Pfizer entered into the 2004 CIA in May 2004, and prior to the time Ausiello, Kilts, and Johnson became directors of Pfizer, and, therefore, cannot form a basis for liability as to those defendants.

There is simply no evidence of the kind of inaction required to establish conscious disregard, much less evidence that any such disregard was undertaken in bad faith. Nor can plaintiffs simply rely on the fact that defendants themselves admit that some off-label promotion of Bextra occurred. Once again, the adequacy of defendants' response is not at issue; rather it is the fact of a response, and the intent with which that response was undertaken, that precludes liability in this case.

2. Geodon

Plaintiffs have failed to come up with any evidence that defendants consciously disregarded allegations of off-label promotion of Geodon when it came to their attention; or that defendants' response was undertaken in bad faith. Once again, the undisputed facts foreclose the possibility of such claims. Far from failing to respond to conduct brought to their attention, the undisputed evidence shows that when the defendants learned of the possibility of improper conduct, they investigated and, upon finding that the company's own policies had been violated, they disclosed their findings to the government and took measures to stop the conduct at issue.[25] (Id. ¶¶ 133-140.) Specifically, more than a year prior to receiving a subpoena from the government in December 2007, defendants removed prescriptions by office-based pediatricians and pediatric/child psychiatric institutions from the Geodon sales representatives' compensation structure. (Id. ¶ 135.) In May 2007, the company excluded all AMA-designated child psychiatrists from the compensation formula.[26] (Id. ¶ 140.) In addition, Pfizer re-trained

[25] As noted earlier, even before the company was aware of the allegations relating to conduct at speaker programs, proactive measures adopted at the direction of defendants to the manner in which speaker programs are conducted had stopped the conduct.

[26] This in fact turned out to be an over-correction that resulted in physicians who treat a substantial number of adult patients being excluded. In October 2007, the company reinstated compensation for sales to child psychiatrists who wrote a significant number of adult prescriptions and for whom at least 40% of their antipsychotic prescriptions were to adult patients. (Id. ¶ 140.)

numerous Geodon speakers. (Id. ¶ 138.) Although the ultimate efficacy of the this response is not in fact at issue, in June 2007, the company's outside counsel issued a report concluding that, at least in part due to these efforts, there was no evidence of any further allegedly improper conduct. (Id. ¶ 137.)

All of the foregoing occurred prior to the time Pfizer received a government subpoena regarding Geodon. There is simply no evidence that defendants made a conscious decision in bad faith to disregard allegations of off-label promotion of Geodon. Instead, the undisputed evidence shows a sustained effort to investigate, report, and remediate any alleged off-label promotion of Geodon.

3. Lyrica

Plaintiffs similarly have no evidence to support the claim that defendants disregarded allegations of off-label promotion of Lyrica, let alone that they did so in bad faith. Instead, the undisputed evidence demonstrates that the defendants once again engaged in a good faith effort to proactively address the risk of off-label promotion before and after the Lyrica launch. Specifically, pre-launch precautions with respect to Lyrica included limiting comparative claims; restricting detailing of doctors likely to write a high percentage of off-label prescriptions; and curbing any discussion of secondary endpoint data. (Id. ¶¶ 121-126 (outlining the numerous measures adopted to mitigate possibility of off-label promotion of Lyrica).) Post-launch, defendants once again took proactive steps. They took additional safeguards with respect to medical information letters (id. ¶ 157), and sent a communication to psychiatrists regarding the lack of a psychiatric indication. (Id. ¶ 122 (letter sent to psychiatrists in conjunction with fibromyalgia launch).)

Moreover, when the defendants learned of alleged violations of the company's internal policies through the routine operation of its reporting system, they investigated, remediated, and

reported the conduct to the FDA and to prosecutors. (Id. ¶¶ 127-131.) Once again, all of this conduct occurred before the government sent a subpoena to Pfizer in July 2007 relating to Lyrica. Thus, as the undisputed evidence demonstrates, defendants investigated each and every allegation of misconduct with respect to Lyrica that was brought to their attention. Again, there is no evidence that they failed to respond to such allegations or that their responses were undertaken in bad faith.

4. Zyvox

Finally, plaintiffs have no evidence that defendants consciously disregarded allegations of off-label promotion of Zyvox, much less that such disregard was in bad faith. The undisputed evidence in fact shows that upon receiving notice of allegedly improper promotion, Pfizer conducted an extensive internal investigation into the matter within 2 months. (Id. ¶ 148.) Pfizer concluded based on this investigation that the conduct was not unlawful. Because Pfizer determined that the conduct was nonetheless inconsistent with Pfizer's internal policies, the company terminated or disciplined 45 employees involved. (Id. ¶ 152 (setting forth the extensive disciplinary action taken).) In addition, the company conducted a sales-force-wide re-training program to prevent such conduct in the future, and issued more extensive guidelines and information addressed to the conduct involved. (Id. ¶¶ 149 (retraining provided to all Zyvox sales colleagues); 151 (clarifying precisely how detail aides should be used and actively discouraging their misuse).) Plaintiffs have no evidence that defendants failed to respond to alleged wrongdoing, much less that such a failure was in bad faith.

5. Other alleged "Red Flags"

In the absence of any evidence to support their claims regarding Bextra, Geodon, Lyrica, and Zyvox, plaintiffs have attempted to cobble together a pile of isolated and unrelated examples of information that came to defendants' attention, stripped these examples of context or

complexity, and deemed them "red flags." Plaintiffs claim that defendants consciously disregarded these "red flags" but have no evidence to support such claims.

Plaintiffs identify roughly three general categories of "red flags": (1) allegations that Warner-Lambert and Pharmacia engaged in off-label promotion before being acquired by Pfizer ("legacy matters"); (2) notices and letters from the FDA regarding the content of promotional literature ("FDA Letters"); and (3) reports issued by Pfizer's internal or external auditors ("audit reports"). What is fatal to plaintiffs' claims is their failure to acknowledge the fact that defendants responded to these supposed "red flags." As described below, the defendants took specific steps to respond to each of the issues identified by plaintiffs.

In the first instance, a significant number of the so-called red flags that plaintiffs identify relate to violations that not only did not take place within the relevant period identified in the complaint; they did not even take place at Pfizer. Since the beginning of 2000, Pfizer has acquired several wholly independent pharmaceutical companies. Approximately two dozen of plaintiffs' red flags relate to conduct that took place at these companies, prior to their acquisition by Pfizer. These legacy matters – which include the conduct described in the 2002 Lipitor settlement, the 2004 Neurontin settlement, and the 2007 Genotropin settlement – did not occur at Pfizer and were beyond defendants' control. Nonetheless, defendants took specific steps to address any ongoing compliance concerns that they raised. With respect to Neurontin, Pfizer investigated the conduct in question and took steps to ensure it did not continue after the acquisition was complete. (Id. ¶ 25.) With respect to Genotropin, Pfizer discovered alleged off-label promotion and disclosed it to the government one month after the acquisition. (Id. ¶¶ 53-55.) Finally, with respect to Lipitor, the conduct involved a single alleged kickback – conduct that has never been repeated at Pfizer. (Id. ¶ 36.)

Plaintiffs also identify 25 FDA letters—the earliest sent in February 2000, and the latest in July 2009. These letters are a key part of the FDA regulatory process, but it bears noting that only a handful of the numerous promotional materials submitted to the government for review raised a concern with the FDA. The undisputed evidence shows that for each of the FDA letters identified by plaintiffs, defendants responded by taking specific and targeted measures to address the government's concerns, frequently ceasing use of the promotional materials at issue or resolving the FDA's concerns by revising the materials and submitting the revised piece to the FDA for review. Thus, for every advertisement with which the government took issue, Pfizer immediately ceased its use or modified its content. See, e.g., (id. ¶ 144.)

Similarly, although plaintiffs identify as "red flags" certain audit reports, they misrepresent their significance, and omit entirely defendants' responses. At the outset, the fact that internal and external audit reports identified and brought to the defendants' and audit committee's attention possible and potential areas for improvement is evidence that Pfizer was discouraging violations of its own policies and procedures, which included a prohibition on off-label promotion, by seeking to improve its efforts to prevent violations. More importantly, plaintiffs once again ignore entirely defendants' responses to these reports. Indeed, for each report, defendants took specific and targeted action to address the concerns raised and corrected any deficiencies. See, e.g., (id. ¶ 162 (reports by head of internal audit to the audit committee).)

The board and audit committee demonstrated an aggressive attitude on compliance issues in response to internal and/or external audit findings. As part of the company's system of compliance checks-and-balances, the committee encouraged its internal auditors to audit compliance-related controls and asked both its internal auditor and its external auditors for candid evaluations. In literally every instance where the internal and/or external auditor expressed concerns about the operation of controls, the audit committee specifically addressed

the matter with management and demanded both a remediation plan and regular updates on progress with the plan.

The undisputed evidence therefore shows that defendants responded in each instance to plaintiffs' alleged red flags. This fact alone precludes liability here. In light of this evidence, plaintiffs will undoubtedly attempt to argue that defendants could have and should have done more to either correct or prevent alleged off-label promotion. Not only is there no evidence that defendants could have and should have done more to either correct or prevent alleged off-label promotion, plaintiffs here cannot establish liability on these grounds as a matter of law. To demonstrate the alleged breach of the duty of loyalty plaintiffs must present proof that defendants' conduct was the product of, not merely negligence – indeed, not even gross negligence – but bad faith. See Stone, 911 A.2d at 369. This requires proof of conduct that "is qualitatively different from, and more culpable than, the conduct giving rise to a violation of the fiduciary duty of care (i.e., gross negligence)." Id. Plaintiffs and their experts, with the benefit of hindsight, may seek to opine on the additional measures defendants might have or should have taken, but they cannot convert their ruminations into proof of defendants' bad faith.

Moreover, to the extent plaintiffs are claiming that defendants should have prevented off-label promotion, there is no legal basis for such a claim. Delaware does not obligate directors or officers to prevent criminal conduct. Plaintiffs got around this legal impediment on the motion to dismiss by claiming that the 2002 CIA and 2004 CIA imposed such a duty. This assertion is flatly contradicted, however, by the terms of the relevant agreements, which the Court is now free to consider on this motion for summary judgment.

B. Plaintiffs Cannot Offer Any Evidence That Defendants Actively Encouraged Off-Label Promotion

Plaintiffs' complaint alleges in general terms that defendants "caus[ed] Pfizer to employ a deliberate and systematic business plan of artificially increasing sales by engaging in unlawful sales and promotion practices." Compl. ¶ 216. In order to prove that the defendants actively encouraged improper conduct, plaintiffs must come forward with evidence that defendants intentionally engaged in wrongdoing that they knew violated the law. See Wood v. Baum, 953 A.2d 136, 142 (Del. 2008). Plaintiffs cannot offer any evidence that defendants purposefully participated in what they knew to be illegal conduct. Rather, all of the evidence in this case is contrary to such a claim and indicates that not only did defendants not encourage wrongful conduct, they undertook numerous steps to discourage off-label promotion.

It is entirely unsurprising that there is no evidence that defendants actively encouraged illegal conduct because the directors and officers who are defendants here were not directly involved in the marketing or promotion of products. Although several of the defendants hold senior management positions within the company they are far removed from decisions regarding how each of Pfizer's 70 plus pharmaceutical products are to be positioned or promoted. In fact, those employees engaged in product positioning and promotion do not report to Mr. Kindler, the CEO, or Mr. Read, the President of the Worldwide Biopharmaceutical Business. Moreover, neither Mr. Kindler nor Mr. Read was elevated to those positions until 2006, well after Bextra had been removed from the market and any off-label promotion of that product had necessarily ceased. Their elevation to those positions also post-dated the company's response to the FDA's Warning Letter regarding Zyvox and its changes to Geodon speaker programs.[27]

[27] Likewise, it should be noted that these events pre-date the time that Dr. Ausiello, Mr. Kilts, Mr. Kindler, and Ms. Nora Johnson joined the board of directors.

Similarly, product marketing and promotion is outside the purview of the board of directors; courts have long recognized that outside directors' responsibilities do not include managing the day-to-day business operations of their companies. Rosenblatt v. Getty Oil Co., 493 A.2d 929, 943 (Del. 1985). Plaintiffs obviously recognize this basic fact as well because they have not asserted a claim of active encouragement against the directors. Any such claim would suffer from the same absence of evidence that dooms the claim against the officers named as defendants.

Not only is there a complete absence of evidence of active encouragement of improper promotion, the undisputed evidence demonstrates that Mr. Kindler, Mr. Lankler, and Mr. Read continually developed state of the art policies and procedures to discourage off-label promotion. In one way or another these policies and procedures addressed each of the categories of conduct at issue in the government investigations. Specifically, these efforts include restrictions on the amount of money physicians who conduct speaker programs can receive; restrictions on the content of speaker programs; speaker training; the creation of the Medical Education Grants Group to remove sales and marketing personnel from the continuing medical education and charitable grant process; restrictions on the number and need for advisory boards; elimination of physician mentorships; restrictions on detailing; changes to the process for setting sales quotas; changes to the compensation of sales representatives; revisions to the process for supplying medical information to physicians; elimination of medical liaisons; changes to the way medical research is published; and changes to disclosure practices relating to research funded by the company. (Defs.' 56.1 Statement ¶¶ 29-33 (outlining the many measures adopted under defendants' leadership to discourage improper conduct by Pfizer personnel).) Any attempt by plaintiffs to argue in hindsight that such efforts should have been made earlier or that better policies and procedures should have been adopted cannot, as a matter of law, give rise to

liability. As set forth above, such arguments sound in negligence and do not suffice to establish a breach of the duty of loyalty. See Stone, 911 A.2d at 369.[28]

C. Defendants' Responses to Allegations of Illegal Conduct and Efforts to Discourage Violations of the Law Are Protected by the Business Judgment Rule and Good Faith Reliance

Because a breach of the duty of loyalty claim holds directors personally liable to the company for acting in bad faith, it is well-established that such claims require proof that defendants "were conscious of the fact that they were not doing their jobs." See In re Sonus Networks, Inc., 499 F.3d 47, 67 (1st Cir. 2007); Gutman v. Huang, 823 A.2d 492, 506 (Del. Ch. 2003); Desimone v. Barrows, 924 A.2d 908, 935-36 (Del. Ch. 2007) ("[D]irectors have to have acted with a state of mind consistent with a conscious decision to breach their duty of care."); Stone, 911 A.2d at 369 ("a failure to act in good faith requires conduct that is qualitatively different from, and more culpable than, the conduct giving rise to a violation of the duty of care (i.e., gross negligence))." A plaintiff asserting such a claim must show that "the fiduciary *intentionally* fail[ed] to act in the face of a known duty to act. In re Walt Disney Co., 906 A.2d at 67. Showing that a defendant's failure to act is intentional is critical to such claims: "By

[28] In the absence of evidence supporting their claims, plaintiffs have spent countless hours seeking to elicit evidence that Pfizer's compliance program was defective. As a matter of law, even if proved, such allegations do not give rise to a breach of the duty of loyalty. Such allegations might be relevant to a breach of the duty of care – the standard for which is gross negligence. The standard for a breach of the duty of loyalty is significantly more demanding. See Stone, 911 A.2d at 369. To the extent the standard of due care is set with reference to what the government expects of such companies, the company abided by the terms of the 2002 CIA and the 2004 CIA. Not only has the government never alleged any breach of these agreements, an independent review organization found Pfizer to be in compliance with the terms of these agreements throughout the relevant period. Moreover, the adequacy of Pfizer's compliance system is not to be equated with a system for reporting issues to management or the board. In cases not involving alleged "red flags," to establish a breach of the duty of loyalty, plaintiffs would need to present evidence demonstrating either: (1) an utter and intentional failure to establish any information or reporting system pursuant to which violations would be brought to their attention or; (2) an intentional effort to make certain that such a system did not bring potential violations to the attention of the defendants. See id. There is no dispute however that Pfizer had a reporting system in place; and that it brought potential violations to the attention of management. Plaintiffs themselves concede as much. See Pls.' Mem. Opp. Defs. Mot. to Dismiss at 16; see also Order at 16.

reinforcing that a scienter-based standard applies to claims in the delicate monitoring context, Stone ensured that the protections that exculpatory charter provisions afford to independent directors against damage claims would not be eroded." Desimone v. Barrows, 924 A.2d at 935.

In the absence of evidence of bad faith or intentional misconduct, the decisions of directors and officers are protected by the business judgment rule. In re Tower Air, 416 F.3d 229, 238 & n.12 (3d Cir. 2005); Kelly v. Bell, 266 A.2d 878, 879 (Del. 1970) (''There is no evidence that any director or officer was motivated by expectation of personal gain, by bad faith or by any consideration other than that of doing what was best for Steel . . . . These acts are governed by the 'business judgment rule.'"); Kaplan v. Centex, 284 A.2d 119, 120-25 (Del. Ch. 1971). Because no such evidence of bad faith exists here, the decisions made by the director and officer defendants to respond to allegations of illegal conduct are entitled to such protection and cannot be the basis of a claim. Accordingly, any attempt by plaintiffs to criticize or second-guess (with the benefit of hindsight) the decisions made by defendants in an attempt to discourage and stop illegal conduct is of no avail. Those decisions, described in detail above, are protected by the business judgment rule.

Moreover, plaintiffs' claims also fail because, as a matter of Delaware statute and case law, the audit committee – with its oversight responsibilities for compliance matters – was warranted in its reliance on both management and outside advisors in addressing alleged off-label sales and marketing activities and other compliance issues. In light of the allocation of responsibilities, the full board was entitled to rely on the reports it received from the audit committee and other recommendations from senior management, and senior management was entitled to rely on persons within the organization with direct responsibilities for managing the sales, marketing and other activities at issue. See In re Citigroup, 964 A.2d at 135 ("directors of Delaware corporations are fully protected in relying in good faith on the reports of officers and

experts"). Under the Delaware Code: "A member of the board of directors, or a member of any committee designated by the board of directors, shall, in the performance of such member's duties, be fully protected in relying in good faith upon the records of the corporation and upon such information, opinions, reports or statements presented to the corporation by any of the corporation's officers or employees, or committees of the board of directors . . ." 8 Del. C. § 141(e); see also In re Walt Disney Co. 906 A.2d at 59 (applied protections of § 141(e) based on reliance upon advice); In re Am. Int'l Group, Inc., 965 A.2d 763, 828 n.246 (Del. Ch. 2009) (reliance on auditors); In re Healthsouth Corp. S'holders Litig., 845 A.2d 1096, 1106 (Del. Ch. 2003) (reliance on reports and recommendations of the CEO).

As the uncontroverted facts show, the audit committee worked in good faith and devoted enormous time reviewing extensive materials before meetings, engaging in robust discussions at meetings, and obtaining recommendations and other information on which it relied from senior management, its CCO and compliance professionals, outside counsel and external auditors about compliance matters. In particular, the audit committee reasonably relied on compliance professionals at virtually every meeting, including annual meetings dedicated to review of the compliance program. It also reasonably relied on auditors' reports about controls, potential violations of corporate policies and remediation efforts directed at any perceived issues or deficiencies. Upon learning of any allegations of possible improprieties, the audit committee reasonably and in good faith relied on the reports and advice from management and advisors, with respect to the scope of the alleged issues, the conduct and investigation findings, the suitability and implementation of corrective measures, and the imposition of disciplinary measures. This reliance was warranted, because both the executives and external professionals on whom the audit committee and full board relied were well-credentialed experts in the areas on which they were furnishing advice. The record thus demonstrates that defendants, acting in good

faith, placed reasonable reliance on the information from these sources in the exercise of oversight duties and decision-making concerning each of the compliance matters at issue, thereby precluding the claims asserted in this case.

II. Plaintiffs' Claims Are Time-Barred By The Applicable Three Year Statute Of Limitations.

Plaintiffs' breach of fiduciary duty claims are also subject to dismissal because they are time-barred by the applicable three-year statute of limitations because the alleged wrong identified in the complaint supposedly occurred four or more years before plaintiffs commenced this action. In re Am. Int'l Group, 965 A.2d 763, 812 (Del. Ch. 2009) (citing 10 Del. C. § 8106(a)); see also Yaw v. Talley, No. 12882, 1994 Del. Ch. LEXIS 35, at *16 (Del. Ch. Mar. 2, 1994) ("the three-year statute of limitations applies to shareholder derivative actions") (citation omitted). The three-year limitations period runs "from the accruing of the cause of such action." 10 Del C. § 8106(a); Yaw, 1994 Del. Ch. LEXIS 35, at *17.

Under Delaware law, "a cause of action 'accrues' . . . at the time of the wrongful act, even if the plaintiff is ignorant of the cause of action." Wal-Mart Stores, Inc. v. AIG Life Ins. Co., 860 A.2d 312, 319 (Del. 2004); see also Albert v. Alex. Brown Mgmt. Servs., No. 762-N, 2005 Del. Ch. LEXIS 100, at *58-59 (Del. Ch. June 29, 2005) ("The law in Delaware is crystal clear that a claim accrues as soon as the wrongful act occurs . . . . . Whether or not the plaintiffs could have sued for damages is not dispositive as to whether the claim accrued.") (citations omitted). In other words, the three-year limitations period governing such claims under Delaware law operates, in essence, as a period of repose. Bovay v. H. M. Byllesby & Co., 27 Del. Ch. 33, 39 (1943) ("Statutes of limitations are intended to prevent the enforcement of stale demands, and are based on reasons of sound policy; they are statutes of repose, intended to exact diligence.") (citations omitted). As a result, plaintiffs cannot pursue claims based on wrongful

acts alleged to have occurred prior to September 9, 2006 – three years before plaintiffs commenced this action. In fact, to the extent plaintiffs' claims are based solely on alleged wrongful conduct pre-dating September 2006, they fail as a matter of law. See, e.g., Yaw, 1994 Del. Ch. LEXIS 35, at *17-19.

Plaintiffs' claims are principally based on conduct alleged to have occurred prior to September 9, 2006, including conduct that took place during the 2002-2004 time period, Opinion and Order (July 13, 2010) at 3-4, 23, and even dating back as early as 2001, id. at 6-7.[29] See also Compl. ¶¶ 81, 89-137, 142-45, 151 (collectively representing examples of plaintiffs' allegations based on conduct for which the limitations period has expired). The principal component of the 2009 settlement agreement relates to alleged promotional activities for Bextra, which ceased being marketed – for reasons unrelated to promotional practices – in April 2005. By definition, conduct involved in the promotion of Bextra occurred more than three years before this action was filed. In addition, the company made disclosure of the government's investigation into the Bextra sales practices in 2006 – which also occurred more than three years before this action was filed. Despite the disclosures, plaintiffs never filed any action or even made a demand under Section 220 of the Delaware General Corporation Law within the applicable limitations period. Plaintiffs' claims based on these allegations are clearly time-barred, as the conduct underlying

[29] The Court noted that even the 2007 deferred prosecution agreement regarding Genotropin "makes clear that all alleged wrongdoing took place prior to Pfizer's acquisition of Pharmacia in April 2003." Opinion and Order at 4 n.2 (citation omitted). The statute of limitations period for such claims has long since expired. Completely disregarding the applicable limitations period in this case, plaintiffs define the "Relevant Period" for purposes of their claims as commencing "on or about May 11, 2004," Compl. at 1, or almost two-and-a-half-years outside the limitations period.

these claims allegedly took place more than three years prior to the date of plaintiffs' initial filing.[30]

Moreover, plaintiffs concede that the 2009 criminal plea – and the related $1.3 billion fine – was based solely on pre-2006 conduct concerning Bextra. (Compl. ¶¶ 135, 142; see also id. at ¶¶ 140, 201 (noting that the $1.3 billion fine concerned only the promotion and sales practices of Bextra).) Specifically, plaintiffs concede that in April 2005, at the FDA's request, "Defendants . . . ceased all sales and promotion activities in the U.S., including the illegal promotion of off-label use for Bextra." (Id. at ¶ 135.) Because plaintiffs' Bextra-related claims are based entirely on conduct that could not have occurred after April 2005, their claims were time-barred as of April 2008 at the latest and accordingly must now be dismissed.

The same is true for the 2004 Neurontin plea agreement by Warner-Lambert as well as the 2007 Genotropin plea agreement by Pharmacia. All of the conduct at issue in each of these investigations occurred prior to September 9, 2006. See Opinion and Order at 3-4 & n.2; Neurontin Information (May 13, 2004) pp. 2-14, attachment A to Neurontin Plea Agreement. Plaintiffs' claims based on this alleged conduct are therefore also beyond the applicable statute of limitations. Likewise, plaintiffs' claims regarding alleged "kickbacks" to health care professionals are based solely on alleged wrongful conduct occurring from January 2001 through December 2004. (Compl. ¶ 142.) Therefore, plaintiffs' claims with respect to kickbacks are also time-barred.

Finally, with respect to any alleged conduct occurring after September 2006 – and within the applicable limitations window – the undisputed evidence shows that Pfizer in all cases

[30] Completely disregarding the applicable limitations period in this case, plaintiffs define the "Relevant Period" for purposes of their claims as commencing "on or about May 11, 2004," Compl. at 1, or almost two-and-a-half years outside the limitations period.

consistently took affirmative steps to respond to potential compliance issues. See supra pp. 31-38. Pfizer thoroughly and in good faith investigated comparative claims regarding Lyrica (late 2006) and Zyvox (2007), and took remedial action in both cases. Id. at 34-35. Likewise, Pfizer took action with respect to re-training Geodon speakers and correcting any off-label promotion of Geodon through 2008. Id. at 33-34. Even if plaintiffs' scattershot allegations regarding the above-mentioned drugs or various "red flags" were to fall within the applicable statute of limitations period, defendants' good faith response to all such issues identified by plaintiffs precludes a finding of liability in this case.

CONCLUSION

For the reasons set forth above, the Individual Defendants' Motion for Summary Judgment should be granted.

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